

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Clinical Trial of Awake Nasotracheal Fiberoptic Intubation: A Comparison of Three Techniques of Conscious Sedation with Remifentanil ,Ketamin and Propofol Without Muscle Relaxants on hemodynamic Parameters in Tempo-mandibular Joint Ankylosis Surgery

Protocol summary

Summary

(1) Objectives: Maintenance and safety of the airway is one of the anesthesiologist's goals and skills with intubation is achieved. Although in some reasons, such as difficult air way, awake-approach is recommended by various techniques such as "conscious sedation" . Using the device for fiberoptic intubation typically is used in the operating room. For the patient comfort and minimizing damage to the tracheal tube during awake intubation by drugs such as remifentanil, ketamine and propofol can be used sometimes under local anesthesia. Awake nasotracheal fiberoptic intubation without muscle relaxants has been reported in some papers. (2) Design: This paper compares three methods of single dose usage of IV-Rremifentanil -Propofol and Ketamine as for "conscious sedation" for fiberoptic intubation device that are evaluated complications of intubation, hemodynamic stability, and study of patients satisfaction in maxillofacial Surgery. The fiberoptic device used by an anesthesiologist and anesthetist is responsible for intubation. (3) Setting and conduct: Fiberoptic intubation with maintenance of spontaneous breathing is a gold standard in cases of difficult airway. The usual treatment for fiberoptic intubation technique can be done under general anesthesia, But for the conscious patients should be careful to do by regional anesthesia with patients tolerance and cardiovascular Hemodynamic stability - provided for safe intubation. (4) Participants including major eligibility criteria: The patients with Physical status of I and age 15 to 60 years are enrolled; The Patients with systemic disease and or taking any medication will excluded. (5) Intervention: In patient with Conscious status setting started by midazolam 0.05 mg/kg and fentanyl 0.1 microgram/kg as intravenous premedication , before fiberoptic procedure, and then route of the patient's air way anesthetized with a local anethia and

then patients will be divided into three groups, the first group: remifentanil, group II: ketamine, group III: propofol is administered as an intravenous infusion, followed awake- nasotracheal fiberoptic intubation is performed (6) main outcome measures:In this method working quickly, complications during intubation, patients satisfaction, and satisfaction anesthesiologist , patient's hemodynamic stability for three-drug techniques (remifentanil, ketamine and propofol) are compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208061674N4**

Registration date: **2012-10-15, 1391/07/24**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-10-15, 1391/07/24

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Supported by Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-11-22, 1392/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial of Awake Nasotracheal Fiberoptic Intubation: A Comparison of Three Techniques of Conscious Sedation with Remifentanyl ,Ketamin and Propofol Without Muscle Relaxants on hemodynamic Parameters in Tempro-mandibular Joint Ankylosis Surgery

Public title

Awake Nasotracheal Fiberoptic Intubation: A Comparison of Three Techniques of Conscious Sedation with Remifentanyl ,Ketamin and Propofol Without Muscle Relaxants .

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria : The patients with Physical status of I and age 15 to 60 years are enrolled; Exclusion criteria : The Patients with systemic disease and or taking any medication will excluded .

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Of Shiraz University Of Medical Sciences

Street address

Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences, Zand Avenue.

City

Shiraz

Postal code

71345-1978

Approval date

2012-08-20, 1391/05/30

Ethics committee reference number

03-2404

Health conditions studied

1

Description of health condition studied

Awake Nasotracheal Fiberoptic Intubation in Temporomandibular joint disorders

ICD-10 code

M24.6

ICD-10 code description

Ankylosis of joint

Primary outcomes

1

Description

Hemodynamic stability in cardiovascular patients for safe intubation

Timepoint

During the intubation procedure

Method of measurement

Blood pressure and heart rate monitoring

2

Description

Level of sedation and the patient's tolerance to the safe intubation

Timepoint

Immediately before - during - and end of Fiberoptic procedure

Method of measurement

Ramsay Sedation score (RSS)

3

Description

Speed in performing intubation

Timepoint

End of procedure

Method of measurement

minute

Secondary outcomes

1

Description

Complications during intubation

Timepoint

After the procedure and 24 hours after surgery.

Method of measurement

Direct observation by the doctor and the patient report

2

Description

Satisfaction of anesthesiologist for intubation

Timepoint

End of the procedure

Method of measurement

Rating of poor (0), moderate (1), good (2), high (3)

3

Description

Waste of time for procedure

Timepoint

End of the procedure

Method of measurement

minute

Intervention groups

1

Description

Single dose -Intravenous infusion of Remifentanyl as "conscious sedation" with dose of 0.75 microgram/kg for fiberoptic intubation through the nose

Category

Treatment - Drugs

2

Description

Single dose -Intravenous infusion of Ketamin as "conscious sedation" with dose of 0.25 milligram/kg for fiberoptic intubation through the nose

Category

Treatment - Drugs

3

Description

Single dose -Intravenous infusion of Propofol as "conscious sedation" with dose of 0.5 milligram/kg for fiberoptic intubation through the nose

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Chamran Hospital

Full name of responsible person

Hamid Reza Eftekharian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences, Zand Avenue.

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

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Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*